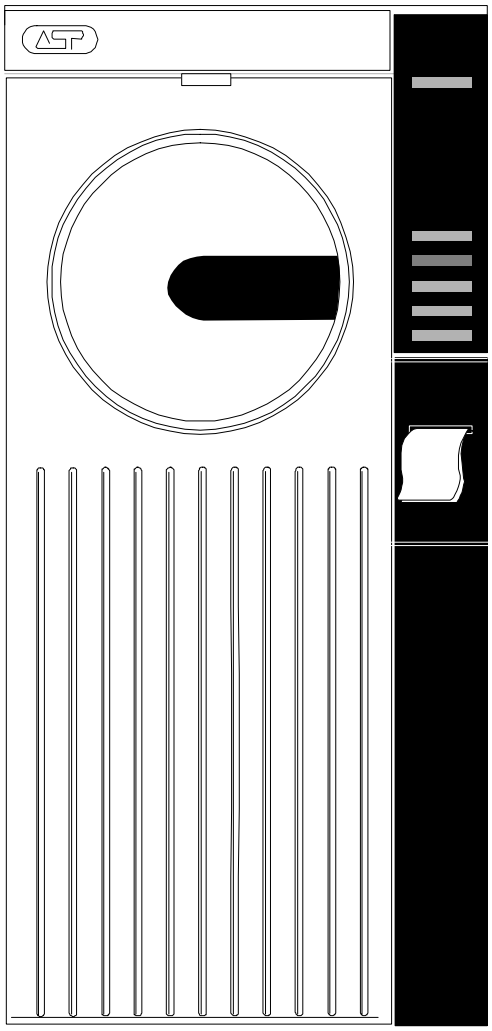
STERRAD® 100S Sterilization System

Routine Maintenance Guide



STERRAD® 100S Sterilization System Routine Maintenance Guide

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824
Authorized EC Representative
Ethicon GmbH
Oststraße 1, D-22844 Norderstedt
CE 0123

USA	Irvine, CA 92618	IT	00040 Pomezia, Roma
FR	92787 Issy-les-Moulineaux	ES	28042 Campo de las Naciones, Madrid
DE	22844 Norderstedt	GB	Ascot, SL5 9EY
CH	8957 Spreitenbach	CA	Johnson & Johnson Medical Products Markham, ON, L3R 0T5
NL	3800 AD Amersfoort	JP	ジョンソン・エンド・ジョンソン 株式会社 〒101-0065 東京都千代田区西神田３丁目５番２号
GR	15125 Maroussi, Athens	A	1190 Wien
SE	19184 Sollentuna	BR	Rodovia Presidente Dutra, Km 154 S.J. Campos-S.P 12240-908
B	1700 Dilbeek	PT	2745-555 Barcarena
CZ	Na Radosti 399 155 25 Praha 5 - Zličín	PL	Johnson & Johnson Poland Sp. z o.o. Szyszkowa 20, 20-285 Warszawa
SK	Plynárenská 7/B 824 78 Bratislava 26	HU	Johnson & Johnson Kft. H-2045 Törökbálint, Tó Park

1-888-STERRAD
(1.888.783.7723)
949.581.5799
www.sterrad.com

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Chapter 1.

Introduction

The STERRAD® 100S Sterilization System is a general purpose, low temperature sterilizer using the STERRAD Process to inactivate microorganisms on a broad range of reprocessable medical devices and surgical instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable, and flexible sterilization method.

A variety of routine maintenance procedures are performed on the STERRAD 100S Sterilizer both at scheduled intervals and as needed. These procedures are detailed in Chapter 3 of this guide.

You must read, understand, and follow the safety information presented in Chapter 2 and throughout this guide. The safety information is provided for your benefit and for the benefit of your instruments and equipment.

Operation Information

This section provides a brief description of the operation of the STERRAD 100S Sterilizer. More detailed information is found in the STERRAD 100S Sterilization System User's Guide and in the STERRAD 100S FSE Troubleshooting Guide. The User's Guide is shipped with the system and is available by contacting the Customer Care Center. The FSE Troubleshooting Guide is only available to those persons who are trained to service STERRAD equipment by ASP Technical Training. Please contact the ASP Customer Care Center for more information: 1-888-STERRAD.

Note: *This following section presents a simplified overview of the sterilizer components.*

The main sterilizer components are shown in the following illustration:

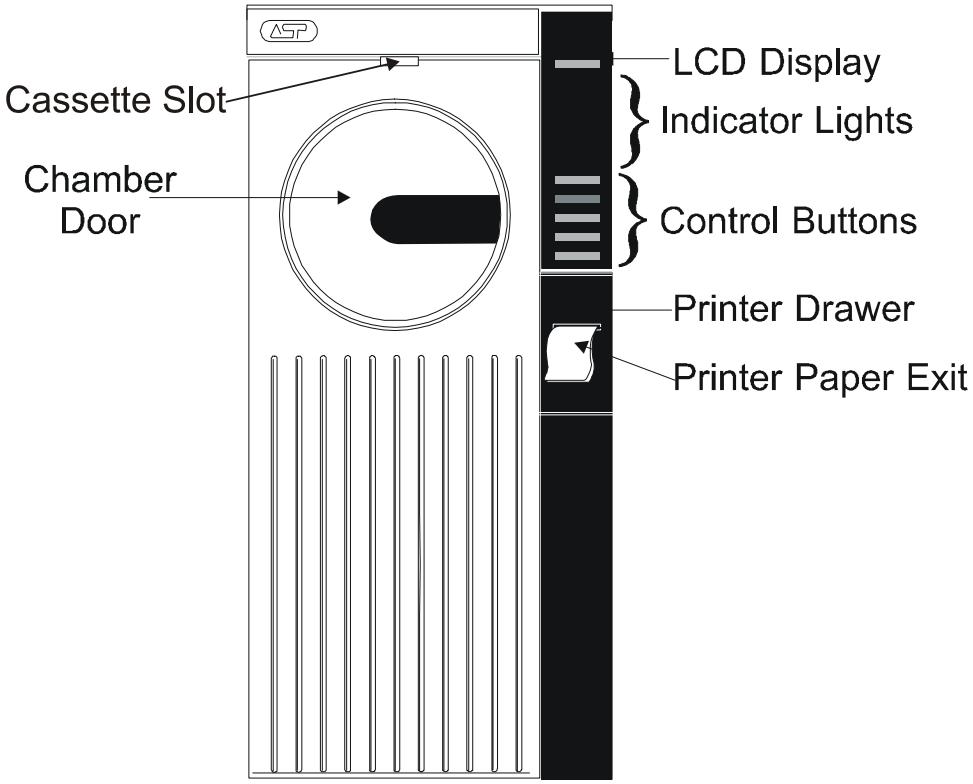

Figure 1. STERRAD® 100S Sterilizer. Your sterilizer may be slightly different in appearance.

Briefly, the sterilizer operates as follows:

- "Ready to Use" is displayed indicating that a sterilization cycle can be started.
- Place the items to be sterilized in the chamber.
- Insert a cassette (if needed).
- Press START.
- The door automatically closes and the sterilization process begins.

When the process is complete, the load can then be used immediately or stored according to your procedures.

Chapter 2.

For Your Safety

Overview

Your safety is of primary concern to ASP. This section provides information on safely using the sterilizer. **You must read, understand, and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions, and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from safely using and maintaining your STERRAD® 100S Sterilization System. Only trained, experienced technicians, who are fully acquainted with the unit, should perform maintenance, repair or adjust the STERRAD 100S System.

Personal Safety and First Aid

- **WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING ITEMS FROM THE STERILIZER AFTER A CYCLE HAS CANCELED. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.
- Direct hydrogen peroxide contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately.
- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician.

- Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately.
- Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN CHAPTER 3 OF THE STERRAD 100S STERILIZATION SYSTEM USER'S GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call the ASP Customer Care Center to determine whether an item can be sterilized in this unit. Information may also be obtained from the device manufacturer.
- The chapter on "Preparing Items To Be Sterilized" in the STERRAD 100S Sterilization System User's Guide contains information about recommended materials; it lists items that can be sterilized in the STERRAD 100S Sterilizer and gives important details on cleaning, packaging, load preparation, etc.
- Do not change the power source without checking the electrical phase rotation. Prior to relocating the STERRAD 100S Sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify and match phase rotation may cause damage to the sterilizer and voids the warranty.
- Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If you plan to disconnect the sterilizer for any lengthy of time, call the ASP Customer Care Center for instructions.

Cassette Handling

- **STERRAD CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT**. Direct contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, immediately drink plenty of water to dilute. Do not induce vomiting. Consult a physician.
- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call the ASP Customer Care Center at 1-888-STERRAD for credit.
- Do not remove used cassettes from the cassette collection box. Dispose of cassettes inside the closed box in normal waste or follow your specific site procedures.
- If it is necessary to handle a used cassette, wear latex, PVC (vinyl), or nitrile gloves. Do not touch your gloved hands to face or eyes.
- Empty or expired cassettes must be replaced prior to starting the cycle as directed by a message on the sterilizer display.

Safe Maintenance

- ONLY EXPERIENCED, ASP-TRAINED TECHNICIANS SHOULD REPAIR OR ADJUST THIS UNIT. REPAIRS AND ADJUSTMENTS SHOULD ONLY BE ATTEMPTED BY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN AND REPAIR THE STERRAD STERILIZER.
- USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND VOIDS THE WARRANTY.

- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

The information in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: **WARNINGS, Cautions,** or **Notes** as appropriate.

- **WARNINGS** are shown in the text in all bold, upper case letters. They indicate events or conditions that can result in serious injury or death.
- **Cautions** are shown in the text in bold letters, and they indicate events or conditions that can result in damage to equipment.
- Notes are shown in the text with the word **Note** in bold. They highlight specific information about the proper use and maintenance of the STERRAD 100S Sterilizer.

Chapter 3.

Routine Maintenance

This chapter presents the routine maintenance, or PM (planned maintenance) procedures that are performed on the STERRAD® 100S Sterilizer. There are two maintenance intervals: PM Level 1 and PM Level 2. These intervals are tracked by the system and the user is notified when the PM is due. The PM Level 1 is performed every 1500 cycles or 6 months whichever comes first. PM Level 2 is performed every 3000 cycles or 1 year, whichever comes first.

In addition, there are a number of "as needed" maintenance activities to be performed. These are presented near the end of this chapter.

WARNING! ONLY EXPERIENCED, ASP-TRAINED TECHNICIANS SHOULD REPAIR OR ADJUST THIS UNIT. REPAIRS AND ADJUSTMENTS SHOULD ONLY BE ATTEMPTED BY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN AND REPAIR THE STERRAD STERILIZER.

USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND VOIDS THE WARRANTY.

Caution: Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If the sterilizer must be turned off for longer than 24 hours, call the ASP Customer Care Center for instructions.

Maintenance Schedule

PM1	PM2	Task Description
Yes	Yes	Inspect Seismic Restraints
Yes	Yes	Replace Vacuum Pump Oil
Yes	Yes	Vaporizer Plate and Vaporizer Maintenance
Yes	Yes	Drain Water From Air Storage Tank
Yes	Yes	Drain Pressure Regulator Moisture Trap
Yes	Yes	Replace Vacuum Pump Oil Filter (Leybold D16A only)
Yes	Yes	Clean Air Filters/Panel Assemblies
No	Yes	Baratron Zero Shift Test
No	Yes	Replace the Catalytic Converter
No	Yes	Replace HEPA Filter
Yes	Yes	Replace Exhaust Filters
Yes	Yes	Clean Door and Inside Chamber Assembly
No	Yes	Clean Platen Surface
No	Yes	Clean Door Seal and Replace Door Seal O-ring
No	Yes	Inspect throttle valve and O-ring. Clean if needed.
No	Yes	Replace Upper Shelf Stops
No	Yes	Replace Electrode Spacers
Yes	Yes	Product Certification
Yes	Yes	Update PM Log

PM Level 1

The PM Level 1 is performed every 1500 cycles or 6 months whichever comes first. When performing PM Level 2, the PM Level 1 procedures should be done first. Following are the items serviced during this PM.

- Inspect Seismic Restraints
- Replace Vacuum Pump Oil
- Vaporizer Plate/Vaporizer Maintenance
- Drain Water From Air Storage Tank
- Drain Pressure Regulator Moisture Trap
- Drain Oil From Vacuum Pump Exhaust Filter Housing (not done on Block 2.0)
- Replace Vacuum Pump Oil Filter (Leybold D16A only)
- Replace Exhaust Filters
- Clean Air Filters/Panel Assemblies
- Clean Door and Inside Chamber Assembly
- Product Certification
- Update PM Log

Seismic Restraint Inspection

1. Disengage the system from the brackets, then move it out of the way.
2. Make sure the bolts are tight, the brackets are in good shape, and the flooring has not cracked or crumbled around the bolts.
3. If there is any problem, even if the brackets are only slightly loose, contact the proper facilities maintenance personnel at the customer site and make sure the brackets are properly tightened.

CAUTION: DO NOT replace the system back on the brackets if they are loose.

Vaporizer Plate/Vaporizer Maintenance

The injector valve vaporizer plate is normally replaced by the customer when the cassette collection box is replaced. If the vaporizer plate needs to be changed at planned maintenance, this procedure should be performed for the customer. See the section on "As Needed Maintenance" in this chapter for detailed removal and replacement procedures. The vaporizer bowl should be wiped with a clean, damp cloth.

Replace Vacuum Pump Oil

***Note**: Always change the pump oil while the pump is warm to prevent condensation in the pump.*

1. Using an 8 mm Allen wrench, unscrew and remove the oil fill plug located at the top of the pump.
2. Remove the cap from the empty bottle in the kit. Place an oil absorbing cloth on the floor inside the machine as close to the drain valve hose as possible. Place the bottle on the cloth. Open the drain valve, place the hose in the bottle and drain the oil.
3. When draining oil from a Leybold D16A pump, insert the funnel in the empty bottle and place it on an oil absorbent cloth, under the valve at the rear of the pump. Open the valve to drain the oil.
4. After the flow has stopped, close the drain valve. Make sure the main circuit breaker is off before proceeding.

   ***Note**: If the used pump oil is excessively dirty, flush out the pump using clean oil.*

5. Open a new bottle of pump oil and replace the cap with the oil filler cap (red tipped). Remove the red tip and cut about 1/6 to 1/4 inch off the cap tip so the oil flows freely.
6. Pour new pump oil (slightly less than one quart) into the oil fill port until oil reaches the raised line at the top of the sight glass (the MAX line on the Leybold D16A). DO NOT OVERFILL or attempt to empty the oil bottle. Some oil may remain in the bottle when the pump oil is at the specified fill level.
7. Re-cap and dispose of the drained oil and the oil absorbent cloth following standard hospital procedures.

Drain the Air Storage Tank

The air storage tank is different on Block 2.0 machines. See the following section for details.

1. Using a towel, cover the drain of the air storage tank, and then slowly open the drain cock. On Block 2 systems, press the trigger or turn the valve to fill the bottle. Then empty the bottle and replace it.
2. When no further water flows from the drain, close the drain cock. Repeat steps 1 and 2 after 10 seconds. Clean up any areas splashed with water.

Drain the Air Storage Tank (Block 2.0)

1. Locate the water collection bottle.
2. Press the air trigger or turn the valve and water flows from the tank into the collection bottle.
3. Remove the bottle, empty it and replace it.

Drain the Pressure Regulator Moisture Trap

1. Place a towel below the pressure regulator trap prior to draining.
2. Press upwards through the towel on the button at the bottom of the trap and permit water to escape.

Replace the Vacuum Pump Oil Filter

This procedure is for the Leybold D16A vacuum pump only. You should complete this procedure before proceeding on to the next one. If you are servicing a Block 2.0 device, proceed to “Drain the Pressure Regulator Moisture Trap.” If you are servicing a pump without the oil return feature, go to “Drain the Exhaust Filter.”

1. Remove the screws and washers attaching the gas ballast valve to the oil casing. Remove the gas ballast valve.
2. Remove the oil filter from the gas ballast hole in the oil casing. Remove any dirt or corrosion found on the gas ballast valve prior to reassembly.
3. Install a new oil filter in the gas ballast hole in the oil casing. Reinstall the gas ballast valve.

Replace the Catalytic Converter/Exhaust Filter

The converter filter core is disposable according to standard facility procedures.

1. Unscrew the converter element from the top of the housing and discard it.
2. Loosen the wing nut on the clamp holding the exhaust filter assembly on the vacuum pump, then open the clamp and remove the filter assembly. Be careful not to damage the O-ring seal.
3. Use a 4 mm Allen wrench to remove the four screws holding the upper and lower sections of the filter housing, then remove the upper section. Be sure the O-ring seal remains in the groove in the lower section.
4. Remove the filter cap from the filter core and dispose of the filter core according to hospital procedures, or, procedures permitting, in normal customer trash.
5. Using a lint free cloth, wipe all oil from the interior of the housing and the mating faces of the housing. Be careful not to unseat the mating surface O-ring seal.
6. Insert a new filter element and replace the filter cap making sure the core is correctly oriented. Be sure that the O-ring seal on the bottom of the filter element is correctly seated.
7. Seat the upper housing section on the lower section and tighten the screws.
8. Install a new converter onto the housing.

Clean Air Filters/Panel Assemblies

1. Lift out the filter over the fan. Gently clean with soap and water. Replace the filter with a new one if necessary.
2. Clean the fan (Block 1.8 only).
3. Thoroughly dry the filter and snap it back in place.
4. Vacuum the screen on the outside of the plasma generator. Carefully vacuum inside the sterilizer.
5. Vacuum the air filter on the rear panel on Block 2 systems.
6. Using a soft cloth dampened with soap and water, clean the exterior panel surfaces.

Vacuum Pump Flush

This procedure should be used ONLY if the drained pump oil was very dirty. It is not a regular PM procedure.

1. Turn OFF the pump and reference the “Replace Vacuum Pump Oil” procedure to drain the used pump oil.
2. Disconnect the vacuum line from the intake tube, turn the main circuit breaker and vacuum pump ON, and pour clean pump oil into the intake tube while the pump is running.

   CAUTION: When flushing the pump, fill it to capacity with pump oil.

3. Allow the pump to run for at least 10 minutes, then turn the main circuit breaker OFF.
4. Drain the pump oil again as described in the “Replace Vacuum Pump Oil” procedure. If the pump oil used for flushing is still dirty, repeat steps 1-3 until the oil is clean.
5. Reconnect the vacuum line to the intake tube and close the drain valve.
6. Open a new bottle of pump oil and replace the cap with the oil filler cap (red tipped). Remove the red tip and cut about 1/6 to 1/4 inch off the cap tip so the oil flows freely.
7. Pour new pump oil (slightly less than one quart) into the oil fill port until oil reaches the raised line at the top of the sight glass (the MAX line on the Leybold D16A). DO NOT OVERFILL or attempt to empty the oil bottle. Some oil may remain in the bottle when the pump oil is at the specified fill level. Replace the oil fill plug on the pump.
8. Dispose of the drained oil following standard customer procedures for lubrication oils.

PM Main Menu

Enter the deep edit mode as shown in Module 6.

PM WARNING = ON (or) OFF OPEN(chng)-CANCEL(next)

ON or OFF indicates the state of the Planned Maintenance warning feature. When this feature has been turned OFF, no messages related to performing planned maintenance are generated. Press OPEN DOOR to toggle the warning between ON and OFF. Press CANCEL to accept the choice displayed.

If the warning feature is ON, pressing CANCEL gives different options for selecting the PM interval. If this feature is OFF, pressing CANCEL transfers you to the Serial Number Edit Menu.

The PM warning is set to ON by default, whenever a loss of battery power occurs, or the number of total machine cycle is reset to zero.

PM Level 1 (2) Edit Menu

The following is displayed:

PM Y (or) N; NEXT PM = XXXX L(X)
OPEN(reset)-CANCEL(next)

Y is yes PM was done. N is no PM has not been done. XXXX is the number of cycles before the PM is due, or the month in which the PM is due and L(X) is level 1 or level 2. If PM is not due on the basis of either months or cycles, XXXX is in cycles. If both months and cycles are due, or both are past due, XXXX is also in cycles. XXXX is displayed in months, if months are due, and cycles are not due. Months are also displayed if months are past due, while cycles are less than past due. If the number shown is a negative number, then it is the number of cycles past due.

The Y changes to N automatically when a PM is due. The level of PM due is indicated on the printout after a cycle has been completed, and on the display in the idle state. You can reset the N to Y by pressing OPEN DOOR; XXXX automatically changes to the level 1 or 2 PM service interval in cycles. If no PM is due, then the number of cycles until the next level 1 or 2 PM is displayed.

1. Press **OPEN DOOR** to store the data, the total machine cycles, and print the information while exiting the Edit mode. The maximum storage capacity is 10 PM service records. When the 11th PM service record is entered, the system deletes the oldest record, re-sequences the existing records and enters the new record in the 10th position. The system prints the PM service history when it is updated.
2. Press **CANCEL** to transfer to the PM Level 1 Cycles Interval menu.

PM Level 1 Cycles Interval

The following is displayed:

PM 1 CYCLES = XXXX
OPEN(chng)-CLOSE(accept)

XXXX is the current Level 1 PM cycles service interval.

1. Press **CLOSE DOOR** to move the cursor to each digit in turn, starting at the rightmost digit, moving left, and wrapping back to the rightmost digit.
2. Press **OPEN DOOR** to increment the digit by 1 ranging from 0 to 9. The Level 1 PM cycles can be programmed to a value between 500 and 2000 cycles, with a default value of 1500 cycles.
3. Press **CANCEL** to transfer to the PM Level 2 Cycles Interval menu.

PM Level 2 Cycles Interval

The following is displayed:

PM 2 CYCLES = XXXX
OPEN(chng)-CLOSE(accept)

XXXX is the default PM level 2 cycles service interval. The default PM level 2 cycles interval is 2 times that of the PM level 1 cycles interval.

1. Press **OPEN DOOR** to change the displayed interval to the next available option, based on the PM Level 1 duration. The PM Level 2 interval can be only 1, 2 or 3 times the PM Level 1 duration, with a range of 500 to 4000 cycles. A duration outside the valid range reverts to the default values.
2. Press **CANCEL** to transfer to the PM Level 1 Months Interval menu.

PM Level 1 Months Interval

The following is displayed:

PM 1 MONTHS = XX
OPEN(chng)-CLOSE(accept)

XX is the current PM Level 1 service interval in months.

1. Press **CLOSE DOOR** to move the cursor to each digit in turn. Press **OPEN DOOR** to increment the digit by 1 ranging from 0 to 9. The interval type months can be programmed to a value between 4 and 12 months, with a default value of 6 months.
2. Press **CANCEL** to transfer to the PM Level 2 Months Interval menu.

PM Level 2 Months Interval

The following is displayed:

PM 2 MONTHS = XX
OPEN(chng)-CLOSE(accept)

XX is the default PM level 2 months service interval. The default PM level 2 months interval is twice that of the PM level 1 months interval.

1. Press **OPEN DOOR** to change the displayed interval to the next available option, based on the PM level 1 duration. The PM level 2 interval can be only 1, 2, or 3 times the PM level 1 duration, within a range of 4 to 24 months. A duration outside the valid range reverts to the default values.
2. Press **CANCEL** to transfer to the Cassette Log Menu.

PM Level 2

The STERRAD Sterilizer requires limited maintenance activity after 1500 cycles (PM1) have been completed and more extensive maintenance after 3000 cycles (PM2). PM2 is performed when the 1500 cycle interval is reached or at one year. Remember: some sterilizers may have older parts. Also, some parts and subsystems created for the Block 2.0 machines are backwards compatible.

Baratron Zero Shift Test

1. Disconnect the capacitance manometer (Baratron) from the chamber and attach it to one side of the T-piece.
2. Connect the T-piece to the chamber.
3. Using an extension harness, connect the one end to the Baratron harness and the other end to the Baratron.

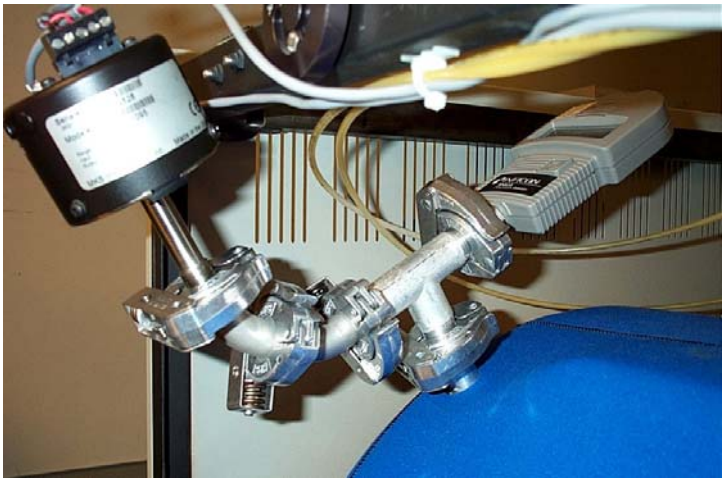

Figure 2. Baratron Zero Shift Test Set-Up.

4. Install the vacuum gauge head to the center of the T-piece. Let the vacuum gauge warm up for about 15 minutes prior to use.
5. Turn on the vacuum gauge. The display indicates 7.6 X 10^2 torr (760 torr) or 760 microns. In the video, the demonstrator indicates the major parts of the TM-20 that need to be assembled.
6. Access the Baratron Zero Test and press START.
7. During pump down, the pressure display on the TM 20 drops below 10 mtorr within 15 minutes.

8. During the test, the pressure displayed on the LCD should remain stable. This is the value of the Baratron. The zero pot should be adjusted to equal the value measured by the TM-20 vacuum gauge.
9. After completion of the test, remove the gauge and re-assemble the vacuum pump.
10. Perform a complete leak back test. If the test fails, inspect the system for leaks.
11. An alternative test is to attach the T-piece to the chamber at the Baratron connection.

Replace the HEPA Filter

1. Remove the HEPA filter body by rotating it counter-clockwise.
2. Remove the new filter from its package, then fasten it into its receptacle. Firmly hand tighten the filter body.

   ***Note**: Do not use Teflon® tape to re-seal the filter.*

3. Discard the used filter according to hospital procedures.

Door and Chamber Procedures

Cleaning the door and process chamber requires a number of steps including the removal of the electrode. The rear of the door should be cleaned during PM 1 and the chamber and electrode examined and cleaned if necessary during that PM. PM2 procedures require that the electrode be removed and it, and the chamber, thoroughly cleaned. During PM2 the door seal O-ring must be replaced. It should be inspected and cleaned as needed during PM1.

The following three procedures, “Replace Door O-Ring Seal,” “Clean Door Surface Assembly,” and “Clean Chamber Assembly,” require that the front and top panels be removed and the door be moved to its service position.

Upon completion of the chamber cleaning and reassembling the electrode and spacers, perform the steps below.

***Note**: Prior to tightening the screws on the front panels on a Block 1.8 system, verify the alignment of the cassette through the cassette door by inserting a cassette.*

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1. Reinstall the panels and reconnect the cassette door assembly cable.
2. Return the door to the normal position. Clean the rear surface of the door with deionized water.
3. Close the chamber door. Close the storage drawer.

Clean Injector Pump Platen Surface

1. Clean the surface of the injector pump platen with deionized water and a lint free cloth.

PM Main Menu

PM WARNING = ON (or) OFF OPEN(chng)-CANCEL(next)

ON or OFF indicates the state of the Planned Maintenance warning feature. When this feature has been turned OFF, no messages related to performing planned maintenance are generated. Press OPEN DOOR to toggle the warning between ON and OFF. Press CANCEL to accept the choice displayed.

If the warning feature is ON, pressing CANCEL gives different options for selecting the PM interval. If this feature is OFF, Press **CANCEL** to transfer to the Serial Number Edit Menu.

The PM warning is set to ON by default, whenever a loss of battery power occurs or the number of total machine cycles is reset to zero.

PM Level 1 (2) Edit Menu

The following is displayed:

PM Y (or) N; NEXT PM = XXXX L(X)
OPEN(reset)-CANCEL(next)

“Y” is yes; PM was done. “N” is no; PM was not done. XXXX is the number of cycles before the PM is due, or the month in which the PM is due and (X) is level 1 or level 2. If PM is not due on the basis of either months or cycles, XXXX is in cycles. If both months and cycles are due, or both are past due, XXXX is also in cycles. XXXX is displayed in months, if months are due, and cycles are not due. Months are also displayed if months are past due, while cycles are less than past due. If the number shown is a negative number, then it is the number of cycles past due.

1. The Y changes to N automatically when a PM is due. The level of PM due is indicated on the print-out after a cycle has been completed, and on the display in the idle state. You can reset the N to Y by pressing **OPEN DOOR**; XXXX automatically changes to the level 1 or 2 PM service interval in cycles. If no PM is due, then the cycles until the next level 1 or 2 PM are displayed.
2. Press **OPEN DOOR** to store the data, the total machine cycles, and print the information while exiting the Edit mode. The maximum storage capacity 10 PM services. When the 11th PM service record is entered, the system deletes the oldest record, re-sequences the existing records and enters the new record in the 10th position. The system prints the PM service history when it is updated:
3. Press CANCEL to transfer to the PM Level 1 Cycles Interval menu.

PM Level 1 Cycles Interval

The following is displayed:

PM 1 CYCLES = XXXX
OPEN(chng)-CLOSE(accept)

XXXX is the current Level 1 PM cycles service interval.

1. Press **CLOSE DOOR** to move the cursor to each digit in turn, starting at the rightmost digit, moving left, and wrapping back to the rightmost digit.
2. Press **OPEN DOOR** to increment the digit by 1 ranging from 0 to 9. The Level 1 PM cycles can be programmed to a value between 500 and 2000 cycles, with a default value of 1500 cycles.
3. Press **CANCEL** to transfer to the PM Level 2 Cycles Interval menu.

PM Level 2 Cycles Interval

The following is displayed:

PM 2 CYCLES = XXXX
OPEN(chng)-CLOSE(accept)

XXXX is the default PM level 2 cycles service interval. The default PM level 2 cycles interval is 2 times that of the PM level 1 cycles interval.

1. Press **OPEN DOOR** to change the displayed interval to the next available option, based on the PM Level 1 duration. The PM Level 2 interval can be only 1, 2 or 3 times the PM Level 1 duration, with a range of 500 to 4000 cycles. A duration outside the valid range reverts to the default values.
2. Press **CANCEL** to transfer to the PM Level 1 Months Interval menu.

PM Level 1 Month Interval

The following is displayed:

PM 1 MONTHS = XX
OPEN(chng)-CLOSE(accept)

XX is the current PM Level 1 service interval in months.

1. Press **CLOSE DOOR** to move the cursor to each digit in turn. Pressing **OPEN DOOR** increments the digit by 1 ranging from 0 to 9. The interval type months can be programmed to a value between 4 and 12 months, with a default value of 6 months.
2. Press **CANCEL** to transfer to the PM Level 2 Months Interval menu.

PM Level 2 Months Interval

The following is displayed:

PM 2 MONTHS = XX
OPEN(chng)-CLOSE(accept)

XX is the default PM level 2 months service interval. The default PM level 2 months interval is twice that of the PM level 1 months interval.

1. Press **OPEN DOOR** to change the displayed interval to the next available option, based on the PM level 1 duration. The PM level 2 interval can be only 1, 2, or 3 times the PM level 1 duration, within a range of 4 to 24 months. A duration outside the valid range reverts to the default values.
2. Press **CANCEL** to transfer to the Cassette Log Menu.

As Needed Maintenance

The following items are serviced on an “as needed” basis and should be checked at both the Level 1 and Level 2 PM intervals.

- Change the cassette collection box.
- Replace the injector valve vaporizer plate.
- Replace the printer ribbon rolls or cartridge.
- Replace the printer paper.
- Reset the time and date display.
- Set the pressure units.
- Use the history menus.
- Clean the sterilizer.
- Master Reset

Changing the Cassette Collection Box

The cassette collection box can hold 30 used cassettes. The cassette box must be changed after 145 cycles. The customer is instructed to change the vaporizer plate every time a new cassette collection box is needed.

If the cassette collection box is not replaced at the proper cycle intervals, the sterilizer does not run any more cycles and the paper printout shows:

CHANGE COLLECTION BOX
NO FURTHER CYCLES CAN BE RUN.

If this occurs, change the cassette collection box immediately. At the same time, change the vaporizer plate.

WARNING! AVOID HANDLING USED CASSETTES. IF IT IS NECESSARY TO HANDLE A USED CASSETTE WEAR LATEX, PVC (VINYL), OR NITRILE GLOVES . DO NOT TOUCH GLOVES TO FACE OR EYES. DISPOSE OF THE CASSETTE COLLECTION BOX IN REGULAR TRASH OR FOLLOW HOSPITAL PROCEDURES.

Figure 3. Do not remove used cassettes from the collection box.

To replace the cassette collection box, do the following:

1. Unlock and open the door on the right side-panel.

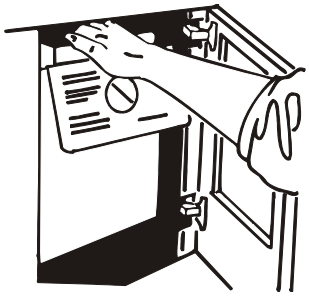

Figure 4. Open the door and remove the cassette collection box.

2. Remove the filled box and close it. Secure both ends with tape.

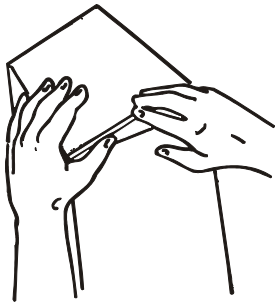

Figure 5. Close the cassette collection box and seal it with tape.

3. Inspect the chute from which the used cassettes slide into the box. It should be free of obstructions. If you must remove a used cassette from the chute, wear latex, PVC (vinyl), or nitrile gloves.

4. Unfold a new cassette collection box. Fold down the lids along the outside of the box. Insert it into the sterilizer. Be sure the instructions face the door and can be read easily.

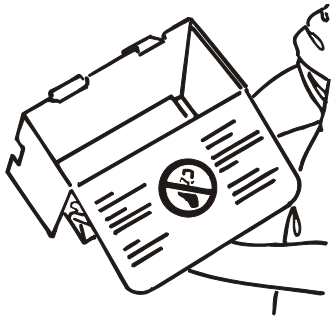

Figure 6. New cassette collection box with lids correctly folded.

5. Close and lock the side-panel door. Go to the following section for details on replacing the vaporizer plate.

***Note**: The microprocessor in the system monitors the time needed for changing the cassette collection box. A new box should be inserted within 10 minutes after removal of the previous box. At least 10 seconds must pass before the microprocessor accepts that a new box has been loaded. A single beep sounds at 10 seconds.*

Replacing the Vaporizer Plate

A vaporizer plate is installed in all STERRAD® 100S Sterilizers. This vaporizer plate minimizes the risk of liquid hydrogen peroxide coming into contact with the load in the chamber. It also helps keep the load and the chamber clean. Operation of the STERRAD 100S Sterilizer without the vaporizer plate in place may result in hydrogen peroxide remaining on the load after a successfully completed cycle. Residual hydrogen peroxide can result in operator contact and/or injury.

Removing the Vaporizer Plate

WARNING! YOU MUST WEAR EYE PROTECTION AND GLOVES WHILE PERFORMING THIS PROCEDURE

1. Replace the vaporizer plate every 30 days or 145 cycles, whichever comes first.

2. Reach into the sterilizer and grasp the protruding end of the vaporizer plate that is closest to you. Pull firmly on the plate; outward and downward so that the lips of the plate unhook from the electrode. You may also want to squeeze the plate slightly and move it outward and downward. Remove the plate from the sterilizer and discard it according to hospital policy.

Installing a New Vaporizer Plate

CAUTION: Please make sure you follow the steps below and hold the vaporizer plate as shown in the illustration. It is very important that the vaporizer plate be correctly installed so that it functions properly.

WARNING! YOU MUST WEAR EYE PROTECTION AND GLOVES WHILE PERFORMING THIS PROCEDURE.

1. Remove the vaporizer plate from its packaging. Hold the plate and insert it as shown in the following figures.

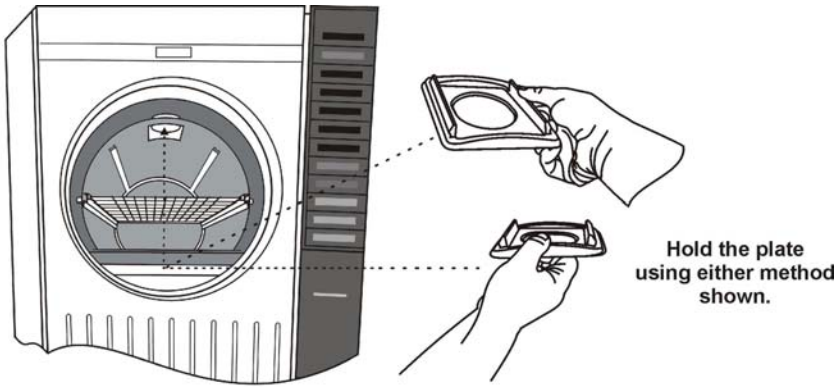

Figure 7. There are two ways to hold the plate for insertion. Choose the one that is most comfortable for you.

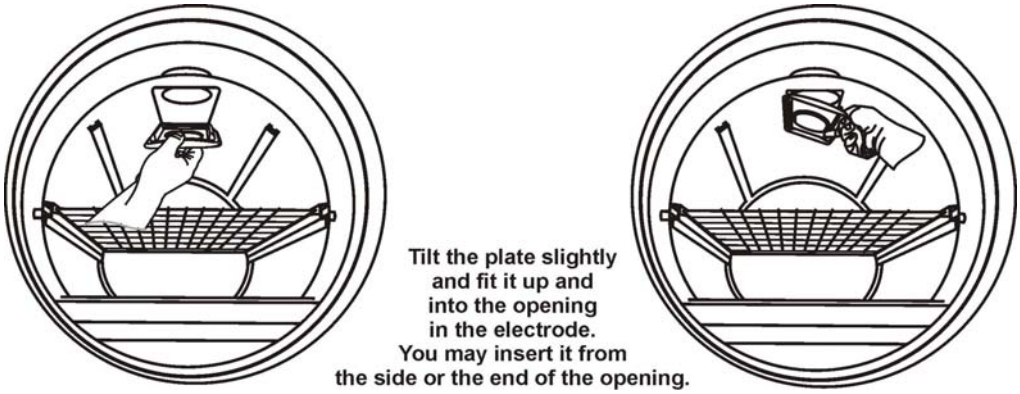
Tilt the plate slightly
and fit it up and
into the opening
in the electrode.
You may insert it from
the side or the end of the opening.

Figure 8. Insert the plate from either side of the opening. The plate fits snugly.

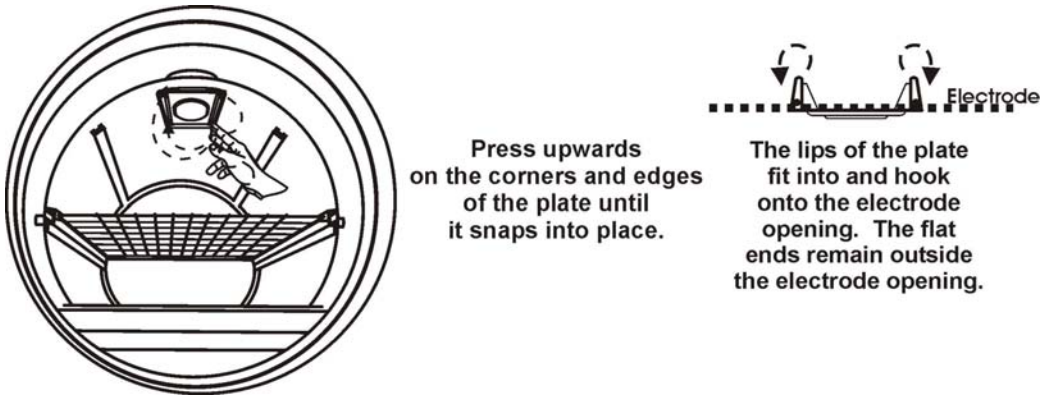

Figure 9. Make sure the plate is correctly placed before using the sterilizer.

Replacing the Printer Ribbon Rolls or Cartridge

To replace the **printer ribbon rolls,** do the following:

1. Open the printer drawer on the control panel.

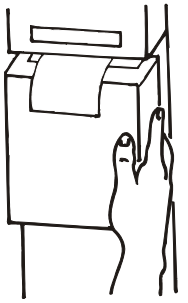

Figure 10. Opening the printer drawer.

2. Hold back the left and right security clips and pull carefully to remove the old ribbon rolls. Discard.

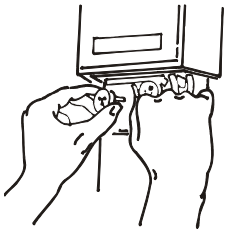

Figure 11. Holding back the security clip to remove the old ribbon roll.

3. Remove the new ribbon rolls from the packaging. Unroll the ribbon about 150 mm (6 inches). Hold back the left security clips and insert the ribbon into the printer slot (red half inside.)

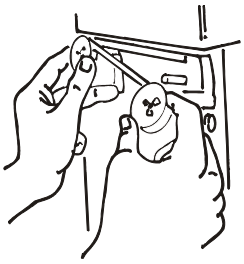

Figure 12. Unrolling the ribbon before mounting the second roll.

4. Hold back the right security clip and insert the other roll into the printer.
5. Turn the right roll clockwise to remove any slack from the ribbon.
6. Close the printer drawer, taking care to ensure that the printer paper exits the printer paper slot.

To replace a **printer ribbon cartridge,** do the following:

1. Open the printer drawer on the control panel.
2. Remove the used cartridge by firmly, but carefully, pulling on the right side, as indicated by the arrow on the cartridge.

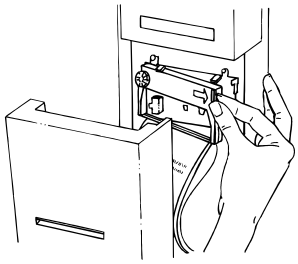

Figure 13. Removing the used printer cartridge.

3. Discard the used cartridge.
4. Insert a new cartridge by aligning the left side of the cartridge with the bracket on the machine. Push on the right side of the cartridge to snap it into place.

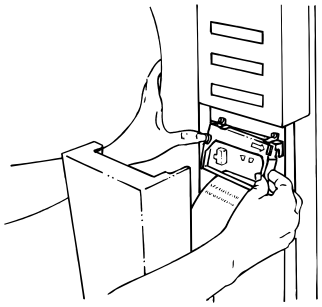

Figure 14. Inserting a new printer cartridge.

5. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.

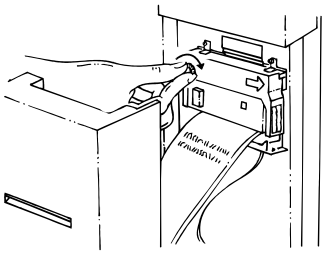

Figure 15. Removing slack from the printer ribbon.

6. Close the printer drawer, taking care to ensure that the printer paper exits the printer paper slot.

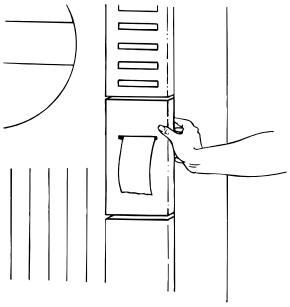

Figure 16. Closing the printer drawer.

Replacing the Printer Paper

To replace the **single roll printer paper,** do the following:

1. Open the printer drawer on the control panel.

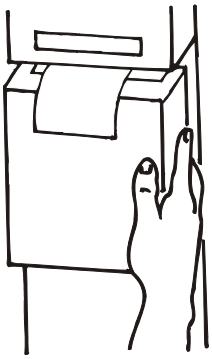

Figure 17. Opening the printer drawer.
(Early version of STERRAD System shown.)

2. Remove the metal rod from the empty paper core and discard the core.
3. Insert the rod into the core of the new paper roll.

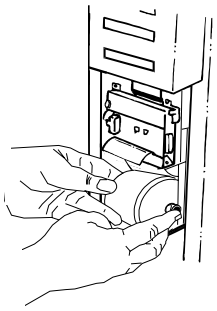

Figure 18. Placing a new paper roll into the retaining slots.

4. Insert the new paper roll so that the paper feeds from the back of the roll. Set the rod in the metal retaining clips.
5. Make sure the paper is smooth and the edge is cut clean.
6. Feed the edge of the paper into the slot behind the printer ribbon until firm resistance is felt. Push up gently on the paper and press **PAPER ADVANCE** until the mechanism begins to pull the paper. Continue pressing **PAPER ADVANCE** until about 70 to 80 mm (3 inches) of paper exits the slot above.

Figure 19. Feeding the paper into the mechanism.

7. Close the printer drawer, taking care to ensure the paper exits the printer paper slot.

To replace the **double roll printer paper,** do the following:

> ***Note**: Do not pull the remaining paper out of the printer mechanism. Instead cut or tear the paper and then press **PAPER ADVANCE** to remove the paper from the printer. This prevents any paper debris from interring with the advance mechanism.*

1. Open the printer drawer on the control panel and remove the large take-up reel containing the yellow backup copies of the cycles.

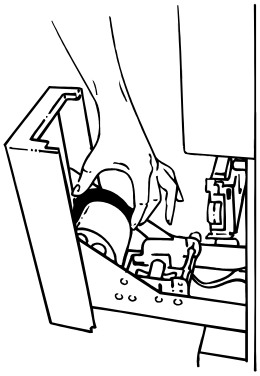

Figure 20. Removing the take-up reel containing the yellow backup copies.

2. Hold the black side of the take-up reel in one hand and, with the other hand, pull off the metal side of the reel.

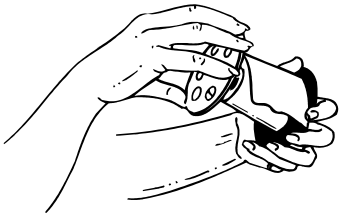

Figure 21. Removing the metal side of the take-up reel.

3. Remove the roll of yellow backup copies and save per hospital policies/procedures.
4. Snap the metal side back onto the reel and replace the reel into the holder.
5. Remove the empty paper core and discard the core.

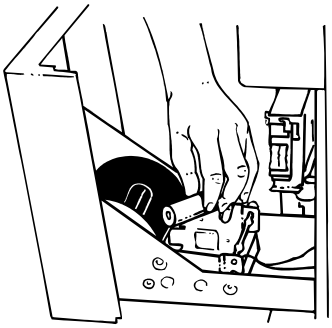

Figure 22. Removing the empty paper core.

6. Place a new paper roll into position so that the paper feeds from the back of the roll.

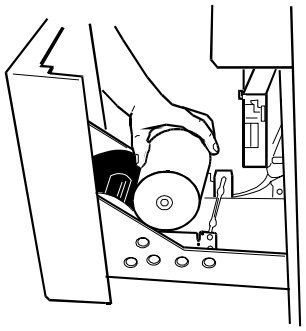

Figure 23. Placing a new paper roll into the proper position.

7. Feed the edge of the paper roll under the metal rod located just behind the paper roll.
8. Feed the edges of both the white and yellow papers into the slot behind the printer.

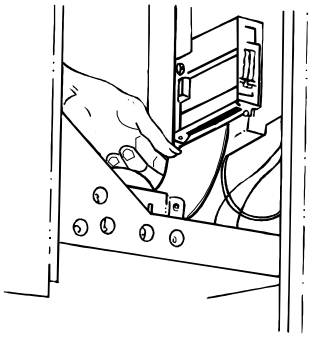

Figure 24. Feeding the paper into the slot leading to the printer cartridge.

9. Push up gently on the paper and press **PAPER ADVANCE** until the mechanism begins to pull the paper. Continue pressing P**APER ADVANCE** until about 150 to 160 mm (6 inches) of paper exits the printer cartridge.

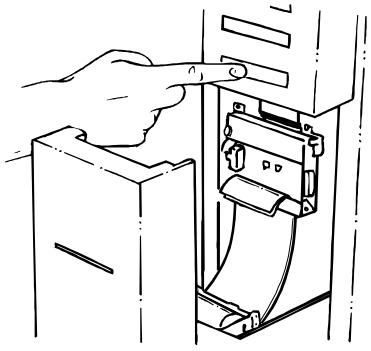

Figure 25. Advancing the paper.

10. Feed the edge of the yellow paper into the slot located on the core of the take-up reel.

Figure 26. Inserting the yellow paper into the slot on the take-up reel.

11. Press **PAPER ADVANCE** to begin winding the yellow paper around the reel.
12. Feed the white printer paper through the slot in the printer drawer and close the drawer.

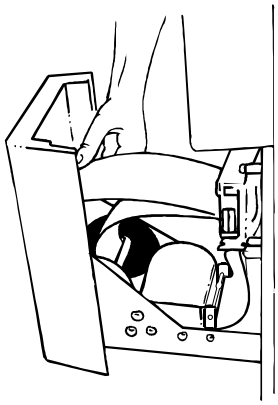

Figure 27, Feeding the white paper through the slot in the printer drawer.

***Note**: To use a single (white paper only) roll, follow the steps above but ignore all references to yellow paper and the take-up reel.*

Resetting the Date and Time

The STERRAD 100S Sterilizer is set-up at installation by a Field Service Engineer to display the time in 12- or 24-hour mode. Be sure to let your engineer know the time method you prefer. You also can change the date

and time as needed. (Change the date and/or time BEFORE starting a cycle.)

To change the **date,** do the following:

1. Open the sterilizer door.
2. Press **START** and **CANCEL** at the same time.
3. The message screen shows the date:

   DATE = MON 02/14/99

4. A flashing cursor appears at the day-of-the-week entry.
5. Press **OPEN DOOR** to change the name of the day of the week.
6. Press **CLOSE DOOR** to accept the desired day of the week. The cursor moves to the next field.
7. Press **OPEN DOOR** to change the displayed numbers.
8. Press **CLOSE DOOR** to accept the desired entry. The cursor moves to the next field.
9. Press **OPEN DOOR** to change the display.
10. Press **CLOSE DOOR** to accept the information. The display changes to the time editing mode.

    Note: *If you are also going to change the time, skip step 10 below, and step 1 in the following section.*

11. At the same time, press **START** and **CANCEL** to exit the date and time editor.

To change the **time,** do the following:

1. Press **START** and **CANCEL** at the same time.
2. Press **CLOSE DOOR** until the time display appears:

   TIME = 01:10:32 PM or 13:10:32

3. A flashing cursor appears at the hour field.
4. Press **OPEN DOOR** to change the displayed hour.
5. Press **CLOSE DOOR** to accept the desired hour. The cursor moves to the minutes field.
6. Press **OPEN DOOR** to change the displayed minutes.
7. Press **CLOSE DOOR** to accept the desired minutes. The cursor moves to the seconds field.

8. Press **OPEN DOOR** to change the displayed seconds.
9. Press **CLOSE DOOR** to accept the desired seconds. The display changes to date.
10. At the same time, press **START** and **CANCEL** to exit the time and date editor.

Clock Mode

1. Press **CANCEL** at any time during the previous date/time setting to set the clock mode. Clock mode selects either a 12-hour clock or a 24-hour clock.
2. Press **OPEN DOOR** to select the clock mode.
3. Press **CLOSE DOOR** or **CANCEL** in Clock Mode to go to the Pressure Units menu.

CLOCK MODE XX
OPEN(chng)-CLOSE(accept)

Setting Pressure Units

The Pressure Units menu displays the units select for pressure. The selected units are also printed at cycle completion. The units can either be in Torr or Pascals.

PRESSURE UNITS = TORR
OPEN(chng)-CANCEL(next)

1. Press **OPEN DOOR** to switch the pressure units between Torr and Pascal. The pressure units are set to Torr by default. The pressure units also reset to Torr whenever a loss of battery power is detected or the number of total machine cycles is reset to zero.
2. Press **CANCEL** to transfer to the history menu.

Using the History Menu

The history menu allows you to print any or all of the following:

- A report of the last 10 cycle cancellations.
- A report of the last 10 barcode read failures.
- A report of the RF reflected power level.
- All three reports at once.

The History Menu displays the following:

HISTORY: PRINT ALL
OPEN(Select)-CLOSE(Prnt)

1. Press **CLOSE DOOR** to print: the last 10 cycle cancellations; the last 10 barcode read failures; and the RF reflected power history.
2. Press **OPEN DOOR** to display the following:

   HISTORY: CANCELLATION
   OPEN(Select)-CLOSE(Prnt)

3. Press **CLOSE DOOR** to print the last 10 cycle cancellations report. Press **OPEN DOOR** to display the following:

   HISTORY: CASSETTE
   OPEN(Select)-CLOSE(Prnt)

4. Press **CLOSE DOOR** to print the last 10 barcode read failures report. Press **OPEN DOOR** to display the following:

   HISTORY: PRINT RF REFL.
   OPEN(chng)-CLOSE(accept)

5. Press **CLOSE DOOR** to print the RF reflected power history report. The display shows the PRINT ALL history menu. Press **OPEN DOOR** to switch between the previous display and the following:

   HISTORY: CLEAR RF REFL.
   OPEN(chng)-CLOSE(accept)

6. Press **CLOSE DOOR** while the above message is displayed, and the RF Reflected Power history records are cleared. The display shows the PRINT ALL history menu.

Cleaning the Sterilizer

The outside surfaces of the STERRAD 100S Sterilizer can be cleaned with a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the STERRAD 100S Sterilizer, call the ASP Customer Care Center at 1-888-STERRAD.

Caution: Do NOT clean the chamber door area with abrasives. The sterilization chamber uses an o-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Master Reset

The master reset must only be done when specifically directed in the Troubleshooting Chapter or by an ASP Customer Care Representative. The master reset is best accomplished by two people. There is NO danger to the operator or the system when performing this operation.

To perform a master reset, do the following:

1. One person remains at the front of the system, the second person moves to the rear of the system.
2. The person at the rear of the system turns the system main power circuit breaker to the **OFF** (DOWN) position. The circuit breaker resembles a large on/off light switch and is located at the bottom, left side of the system.
3. The person at the front of the system presses and holds **CANCEL** on the control panel and instructs the person at the rear of the system to switch the circuit breaker to the **ON** (UP) position while continuing to hold the **CANCEL** button for 10 seconds or until the system beeps. When the system beeps, the master reset is complete.
4. The person at the front of the system verifies the master reset was successful by viewing the message on the display. The display shows a series of numbers/letters in the following format XX-XXXXX-X-XXX.

Chapter 4.

Technical Data

Physical Specifications

System Dimensions	
Dimensions	765 mm W x 1660 mm H x 1020 mm D (30" W x 65.5" H x 40" D)
Appearance	FED color specification #26408 Block 2 has a custom color
Weight	Approximately 325 Kg (700 lbs)
Shipping Weight	Approximately 350 Kg (750 lbs)
Chamber	
Volume	173 liter (6.1 cubic feet)
Usable Volume	100 liter (3.5 cubic feet)
Inside Length	810 mm (32 inches)
Inside Diameter	510 mm (20 inches)
Shelving	
Upper Shelf Dimension	700 x 425 mm (28" x 17")700 x 426 mm (28" x 16.7") Block 2
Lower Shelf Dimension	760 x 425 mm (30" x 17")760 x 325 mm (30" x 12.8") Block 2
Shelving Strength	25 kgs (55 lbs) uniformly distributed per shelf
Shelving Materials	Passivated stainless steel and polyethylene
Top Shelf Adjustment	Removable. Shelf slides out of chamber to one half of its length.
Bottom Shelf Adjustment	Fixed

Environmental Conditions

Transport and Storage	
Ambient Temperature	-40° to +70° C (-40° to 158° F)
Relative Humidity	10 to 100% including condensation
Atmospheric Pressure	500 hPa to 1060 hPa
Operation	
Ambient Temperature	+10 to 40° C (50 to 104° F)
Altitude	-100 to 3000 m above msl (-330 to 10,000 ft above msl)
Relative Humidity	0 to 95% RH, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Surface	The floor at the installation is flat and level to + 5 mm/M.
Installation Space Requirements	In operation, the system shall not be placed closer than 50 mm (2 in) to a wall at the rear and/or sides of the system. The system should be installed in a space of sufficient size to permit access to all four sides of the system when the system is rolled away from the rear and/or side walls a distance of 3 meters (10 ft), the extent of the power cord. Service access should allow for a minimum clearance of one meter (3 ft) on all sides of the system.
Mobility	The sterilizer is designed to be free standing and self contained with no required connections other than the electrical power cord. The sterilizer is equipped with wheels that allow it to be rolled easily from one location to another. The unit is also equipped with adjustable feet at the front of the unit if leveling is required.

Electrical Requirements

Voltage Specification	
IMPORTANT WARNING!	Prior to relocating the sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify phase rotation may cause damage to the system and void the warranty.
208V 60 Hz Power 200V and 208V (Block 2)	For versions employing 208V, 60 Hz power, the sterilizer requires a NEMA L21-20 five wire grounding twist lock outlet attached to a dedicated 20 Amp 3 phase 208 Volt circuit with separate neutral and ground conductors.
380 - 415V 50 Hz Power 380V, 398V and 415V (Block 2)	The sterilizer requires a five wire grounding outlet attached to a dedicated 10 AMP, 3 phase, 380V circuit with separate neutral and ground conductors.
Phase Rotation	The system requires CBA phase rotation. The phase rotation is adjusted to match the system requirements at installation.
Power Calculation	Phase A 228 Watt-hours per cycle Phase B 158 Watt-hours per cycle Phase C 177 Watt-hours per cycle Total 563 Watt-hours per cycle
Heat Generation	1919 Btu per cycle

Heater Impedance

Heater Location	Type	Impedance
Door	Block 2	190 Ohms
Chamber	Block 2	100 Ohms
Chamber top	Block 1.8	50 Ohms
Chamber bottom	Block 1.8	50 Ohms
Chamber rear	Block 1.8	190 Ohms
Door	Block 1.8	50 Ohms

Thermocouples

Thermocouples	Measurement	Location
TC1	42°-50° C	Top of chamber behind injector valve
TC2	42°-50° C	Bottom of chamber near door
TC3	42°-50° C	Middle of door
TC4	42°-50° C	Edge of door

Standards

Agency	Description
EPA/OSHA	Maximum hydrogen peroxide ambient concentration: less than 1 PPM (8 hour weighted average). Tested average was 0.014 PPM.
NEC	The system meets all applicable National Electrical Code (US) standards.
VDE	VDE 871 certification. Report Number 91287V.
FCC	The system meets all FCC Class A, IEC CISPR requirements.
CSA	All electrical components are CSA approved. Block 2 meets CSA requirement certificate number LR-103178-1
IEC	IEC 601-1 Medical Equipment Safety Certification. File Number 112 MT 14880.
LA	City of Los Angeles Electrical Testing Lab Approval. Application Number 330300
TUV	Meets TUV requirements.
NSTA	The shipping container includes an integral pallet which meets US and International standards. The package provides protection for the machine to pass NSTA tests ASTM D-999 and FED-STD-101.
NRTL/C	Block 2 meets UL standard 1262-Laboratory Equipment